

Procedure and Process Summary: Trofile Test Request

AIDS Drug Assistance Program (ADAP)

Virginia Department of Health (VDH)

VDH ADAP Trofile assay access program only applies to ***uninsured ADAP clients***. This document summarizes all processes of the program in the following categories:

- (1) pre-authorizations procedures,
- (2) selection collection site and scheduling draw appointment,
- (3) laboratory collection and initial sample processing,
- (4) final result reporting, and
- (5) prescription authorization.

Pre-Authorizations Procedures

1. Provider obtains the following documents from the Division of Disease Prevention ADAP website:
<http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/Programs/ADAP/support.htm>, or by contacting the Virginia Department of Health (VDH) Laboratory Liaison at (804) 864-8000:
 - (a) VDH ADAP Medication Exception Form
 - (b) VDH Monogram Biosciences Client Consent and Release of Information Form
 - (c) List of VDH Contracted Laboratory/Collection Sites.
2. Provider faxes the completed VDH ADAP Medication Exception form and copy of signed consent form to the VDH Laboratory Liaison at (804) 864-8050. VDH Lab Liaison to contact provider to obtain name and address of selected laboratory/collection site. Laboratory Liaison will enter information in the "Test Ordered" section of the Monogram Biosciences VDH Test Authorization Form.
3. Laboratory Liaison verifies ADAP enrollment. If client is not on ADAP, Laboratory Liaison notifies provider's office to send the client to the nearest local health department (LHD) to apply for ADAP. If client is new and eligible for ADAP, a CHS1 or equivalent, verifying eligibility is faxed from the local health department to the Laboratory Liaison.
4. Upon verification of ADAP enrollment, the Laboratory Liaison reviews the ADAP Medication Exception Form. If there are any questions, the Laboratory Liaison contacts medical provider for resolution. The Laboratory Liaison forwards the VDH ADAP Medication Exception Form to the Assistant Director of HIV Care Services, or designee for signature.

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5. Once client is approved for the Trofile test, Laboratory Liaison confirms provider contact information and completes the Monogram Bioscience VDH Test Authorization Form. After Laboratory Liaison completes form review, the Assistant Director of Health Care Services or designee reviews and signs the VDH Monogram Biosciences VDH Test Authorization Form.
6. VDH Laboratory Liaison notifies Monogram Biosciences of approval of Trofile test request by faxing the approved Monogram Biosciences VDH Test Authorization Form. Laboratory Liaison sends Monogram Biosciences the list of VDH contracted sample collection sites at program inception and send updates with each sample collection site enrollment into the program.
7. Laboratory Liaison files the VDH ADAP Medication Exception Form, and the Monogram Biosciences Test Authorization Form in the Trofile pending file.

Selection collection site and scheduling draw appointment

8. Upon receipt of approved Monogram Biosciences VDH Test Authorization Form, Monogram Biosciences sends the two part Monogram Biosciences Trofile assay "Test Request Form" to the medical provider. Monogram sends the two (2) PTT tubes to the medical provider's selected collection site as indicated on the Monogram Biosciences VDH Test Authorization Form if the collection site is either a VDH local health department or independent lab collection site.
9. Medical provider sends the completed two part Monogram Biosciences Trofile Test Request Form and the signed VDH Monogram Bioscience Client Consent Form with the client to the laboratory/collection site. Trofile testing will not be performed if client consent form is not signed.

Laboratory collection and initial sample processing

10. Medical provider's selected sample collection site will collect and process sample for Trofile assay according to Monogram Biosciences specifications included in the laboratory sample collection protocol. Sample collection site to contact Monogram Biosciences to have specimen shipped per Monogram Biosciences Courier and Shipping Protocol. Sample collection site will fax copy of signed consent form and air bill to Laboratory Liaison at (804) 864-8050 after sample has been retrieved by Monogram Biosciences' designated courier service. Sample collection site to retain back copy of Monogram Biosciences Test Request Form, and if desired by the collection site, a photocopy of the signed consent form.

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Final result reporting

11. Monogram Biosciences forwards test results to medical provider and Laboratory Liaison. A Trofile test result is verification of performance of testing. Results are expected to be forwarded within 14 days of Monogram's receipt of the client's specimen.

Prescription authorization

12. If Trofile test results are positive (R5 trophotype), the Laboratory Liaison notifies the medical provider by telephone of approval of use of Maraviroc. Laboratory Liaison will document provider notification by recording date, time, and name of contact on VDH's copy of the Trofile assay final test report. Laboratory Liaison will also fax approved ADAP Medication/Lab Exception Form noting approval of use of maraviroc to local health department ADAP Coordinator.
13. Laboratory Liaison retains a copy of test results as proof of verification to approve invoices when received and compares to faxed copy of air bill for reconciliation of Monogram Biosciences testing charges.
14. Medical provider(s) and local health department(s) to follow their existing procedure(s) for filling ADAP prescriptions.

**Please direct any questions to the Laboratory Liaison,
Phyllis Morris, at 804-864-8000 or Phyllis.Morris@vdh.virginia.gov**